IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN EXHIBIT A TO PLAINTIFFS' NOTICE OF ADOPTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF JANET E. TOMEZSKO, M.D.

In Wave 3 of this litigation, Plaintiffs adopt the *Daubert* motion they filed as to the general-causation opinions of Janet Tomezsko, M.D., in Wave 2. *See* Pls.' Notice of Adoption (Dkt. 2810). The Court has not yet ruled on that Wave 2 motion, but it has ruled on the Wave 1 *Daubert* motions filed. Defendants Ethicon, Inc., Johnson & Johnson, and, where applicable, Ethicon LLC (Ethicon) respectfully request that this Court again deny Plaintiffs' motion for the reasons expressed in Ethicon's Wave 2 response (Dkt. 2539) incorporated here and as supplemented by the reasons set forth below based on the Court's Wave 1 rulings, which provide guidance on how the Court may rule on Wave 2 motions.

ARGUMENTS AND AUTHORITIES

I. Dr. Tomezsko's chronic inflammation opinion is based on her review of the medical literature—a well-accepted methodology under *Daubert*.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a

physician can draw upon her clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Dr. Tomezsko used this scientifically reliable methodology here. Her report contains multiple references to the scientific literature (*see generally* Ex. A to Pls.' Mot. (Dkt. 2435-2), Tomezsko Report) and she relied on that literature along with her clinical experience in forming her opinions. But, relying on isolated excerpts of Dr. Tomezsko's deposition testimony and then taking them out of context, Plaintiffs argue that the literature relied upon is "selective" and that Dr. Tomezsko "ignore[d] scientific scholarship refuting them." *See* Pls.' Mem. (Dkt. 2440) at 4.

Plaintiffs' argument fails for two reasons. First, the testimony Plaintiffs rely upon does not support their argument. Plaintiffs' counsel asked, in general terms, whether Dr. Tomezsko was aware of literature that "suggests" that polypropylene mesh used in the TVT can result in chronic inflammation. *Id*. at 5; *see also* Ex. 1, Tomezsko 6/27/16 Dep. Tr. 49:21-50:1, 50:8-12. Dr. Tomezsko responded that she looks "at the literature for what it proves, not what it suggests." Ex. 1, Tomezsko 6/27/16 Dep. Tr. 50:2-3. Even though Dr. Tomezsko asked counsel to identify specifically the literature counsel was referring to (*id*. at 50:16-18), which counsel did not do, Dr. Tomezsko's explanation that she looks to literature for what it proves, not what it suggests, is sufficient explanation, (*cf. Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *12 (S.D.W. Va. Sept. 29, 2014); *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *10 (S.D.W. Va. May 5, 2015)). Unlike both *Sanchez*

and *Wilkerson* where Dr. Margolis was asked about specific literature,[1] Plaintiffs' counsel did not, and still has not, identified any specific literature that allegedly is contrary to Dr. Tomezsko's opinions. Rather, Dr. Tomezsko explained, in the same general terms she was asked, that she looks to literature for what it proves, not what it suggests.

Second, even if she believes "there is some [literature] out there" that counsel failed to specifically question about (Ex. 1, Tomezsko 6/27/16 Dep. Tr. 50:15-16), this is no concession that she failed to account for contrary literature. Viewing her testimony in full on this issue and in the context it was given, shows that she explained why she rejected this nonspecific contrary literature.

> Q. Okay. Doctor, if there is literature out there that would show that there is a chronic inflammation associated with the implantation of the TVT Retropubic device, is it fair to say you disagree with that literature?
>
> . . .
>
> A. I would disagree with that literature based on the multiple meta-analysis, long-term studies showing the low rate of complications that we actually see such as erosions or pain. So that's what matters.

Id. at 50:20-51:7.

Contrary to Plaintiffs' argument that Dr. Tomezsko made "no attempt" to review contrary literature on chronic inflammation (Pls.' Mem. (Dkt. 2440) at 5), she did. And she sufficiently explained her reasons for rejecting it, just as Dr. Margolis did in his reformed opinions in *Wilkerson*. *See* 2015 WL 2087048, at *10; *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4944702, at *3 (S.D.W. Va. Aug. 30, 2016) (denying plaintiffs'

[1] *See Sanchez*, 2014 WL 4851989, at *12 (failing to explain why he rejected the *Nilsson* study); *Wilkerson*, 2015 WL 2087048, at *10 (reforming his opinion to now explain the basis for rejecting the *Nilsson* study).

Daubert challenge because Dr. Schwartz "explained why he did not rely on or discounted the studies the plaintiffs claim he should have reviewed"); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493556, at *3 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. McKinney). Plaintiffs' contrary-literature argument is meritless and should be rejected.

II. Dr. Tomezsko is qualified to testify about risks that are within the common knowledge of physicians.

Plaintiffs claim, without support, that Dr. Tomezsko offers opinions about the adequacy of the TVT IFU on the same basis as did the expert in *Sederholm v. Boston Scientific Corp.*, No. 2:13-cv-12510, 2016 WL 3282587 (S.D.W. Va. June 14, 2016)—"based solely on the risks [she] observed in [her] practice." Pls.' Mem. (Dkt. 2440) at 6. Yet, Plaintiffs point to no warnings opinions where Dr. Tomezsko has done so, nor did she. On the contrary, the opinion that Plaintiffs challenge—*i.e.*, that the TVT IFU "presents the risks of the device which would not otherwise be known by pelvic surgeons" (*id.*)—is one grounded in the scientific method, the law, within her expertise, and consistent with the Court's Wave 1 rulings.

It is well-established that a medical device manufacturer has no duty to warn of risks within the common knowledge of a physician, the learned intermediary. *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 265-66 (5th Cir. 2002) (applying Louisiana law applicable in *Richard* and *Blackwell*); *Reece v. AstraZeneca Pharms., LP*, 500 F. Supp. 2d 736, 750-51 (S.D. Ohio 2007) (applying Ohio law applicable in *Gullett* and *Van Wyck*); *Smith v. Louis Berkman Co.*, 894 F. Supp. 1084, 1092 (W.D. Ky. 1995) (applying doctrine under Kentucky law applicable in *Woosley*); *Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. Ct. App. 1997) (applying Illinois law applicable in *Soltanshshi* case); *Ziglar v. E. I. Du Pont De Nemours & Co.*, 280 S.E.2d 510, 515 (1981) (applying North Carolina law applicable in *Ward*); *Harden v. Danek*

Med., Inc., 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998) (applying Tennessee law applicable in *Mincey*, *Phillips*, and *Williamson*).[2]

Dr. Tomezsko testified repeatedly of the risks that are well known to pelvic-floor surgeons and how physicians become aware of this information beginning in medical school and, progressing through the physician's career, from the physician's clinical experience, attending professional meetings, and staying current with research and review of the literature. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 131:21-132:9, 132:24-133:7, 137:23-138:9, 147:17-149:19; *see also* Ex. A to Pls.' Mot. (Dkt. 2435-2), Tomezsko Report at 23-24. Her opinions on this issue are consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (providing that information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device").[3]

Dr. Tomezsko is qualified to offer these opinions. She is a fellowship-trained pelvic-floor surgeon who is board certified in both obstetrics and gynecology and female pelvic medicine and reconstructive surgery. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 19:18-19, 21:8-14, 22:1-8. She is a

[2] The state law applicable to each of the plaintiffs name in Plaintiffs' Exhibit A also follow the learned-intermediary doctrine. *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La. 1995) (applying Louisiana law); *Simmons v. Boston Scientific Corp.*, No. 2:12-cv-07398, 2015 WL 2137145, at *2-3 (S.D.W. Va. May 7, 2015) (applying North Carolina law); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) (applying Illinois law); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 768 (Ky. 2004) (applying Kentucky law); *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991) (applying Ohio law); *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686, 701 (Tenn. 2011) (applying Tennessee law).

[3] *See also* Restatement (Third) of Torts: Products Liability § 2, cmt. j (stating generally that a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users"); Restatement (Second) of the Law of Torts §§ 388(b), 402A, cmt. j.

specialist in female pelvic medicine and reconstructive surgery (*id*. at 21:4-7), conducts research in this area of medicine (*id*. at 22:11-21), is involved in clinical studies (*id*. at 23:5-24:3), and trains fellows and residents (*id*. at 114:7-8). Over her career, she has implanted between 1,000 and 1,500 TVT devices, and removed around five or so. *Id*. at 27:6-9, 29:24-30:3, 176:8-177:5.

As an experienced pelvic-floor surgeon, she is well-versed in the risks that are known by pelvic floor surgeons and qualified to give opinions about those risks. *United States v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (allowing FDA to offer evidence by affidavits of two medical experts as to what information is within common knowledge of physicians in a misbranding case). She need not be familiar with FDA rules or regulations to give this testimony. *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *6-7, 15 (S.D.W. Va. Apr. 24, 2015); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-04, 719 (S.D.W. Va. 2014) (finding Drs. Rosenzweig and Blaivas adequately experienced physicians to testify about risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *13-14 (S.D.W. Va. May 19, 2016) (finding Dr. Shull qualified to testify "on the completeness and accuracy of the [mesh product's] warnings from a clinical perspective"). Indeed, a physician is qualified to make a comparison between "the risks [the physician] perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Trevino*, 2016 WL 2939521, at *13-14 (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). This principle is consistent with the rulings this Court recently issued for Wave 1 cases—namely, that a urogynecologist is qualified to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant

IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, *3 (S.D.W. Va. Aug. 31, 2016).

In addition to her training, clinical experience, and general knowledge as a pelvic-floor surgeon, Dr. Tomezsko draws on her knowledge of complications discussed in the medical literature, statements of leading medical societies, and core curriculum materials in formulating her opinions about commonly known risks. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 147:6-149:20, 164:11-175:15 (discussing various scientific literature relied upon in forming her opinions). Based on this support, Dr. Tomezsko is qualified to form the opinion that Plaintiffs challenge—*i.e.*, that the TVT IFU "presents the risks of the device which would not otherwise be known by pelvic surgeons." *See* Pls.' Mem. (Dkt. 2440) at 6. Indeed, as a practicing surgeon who went through years of medical education and training, has extensive clinical experience with pelvic-floor surgeries, trains fellows and residents, and keeps up with the medical literature, Dr. Tomezsko is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic-floor surgeries. Indeed, only a physician with such training and experience could testify as to the common knowledge of surgeons who perform these surgeries.

And she does so, not based on the risks observed in her practice as Plaintiffs argue, but on her knowledge as a pelvic-floor surgeon, her experience, and her review of the literature. Plaintiffs' reliance then on *Sederholm* is misplaced. Unlike the physician expert in that case, Dr. Tomezsko is not offering an opinion that the TVT IFU is adequate because it included risks she has observed in her own practice. *Compare Sederholm*, 2016 WL 3282587, at *13, *with* Ex. A to Pls.' Mot. (Dkt. 2435-2), Tomezsko Report at 24.

Ethicon is mindful of the Court's Wave 1 rulings and that experts without additional regulatory expertise on product labeling and compliance cannot testify "about what an IFU

should or should not include." *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4557036, at *3. Dr. Tomezsko will not be offering opinions about what should or should not be included in an IFU. Ethicon respectfully submits, however, that risks that are within the common knowledge of physicians are risks that would not, as a matter of logic, be included in an IFU. This logical result, however, does not mean that an expert's common-knowledge testimony should be excluded under the Court's exclusionary "additional expertise" directive. Instead, the Court's directive goes to the lack of expertise in regulatory requirements and compliance, not whether a particular risk is within the common knowledge of physicians. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015) (distinguishing between an expert's expertise "in the requirements for product labeling" and the expert's qualifications as a practicing physician to testify about risks provided in the text of the product's labeling).

In accordance with this distinction and the Court's limitations, Dr. Tomezsko will not testify about the regulatory requirements for product labeling for the IFUs at issue here or what the IFU should or should not include. But she is qualified by education, training, and experience to give opinions about what risks are within the common knowledge of surgeons who perform pelvic floor surgery. Any disagreement Plaintiffs may have with Dr. Tomezsko's opinions on this issue goes to weight, not admissibility.

III. Dr. Tomezsko's statements about removal of the TVT are neither ambiguous nor Dr. Tomezsko's *ipse dixit.*

It is hard to discern the point Plaintiffs are trying to make with their "removal" argument. On one hand, it appears they take issue with Dr. Tomezsko's unwillingness to divulge what she perceives as confidential information and that testimony to this effect is ambiguous (*see* Pls.' Mem. (Dkt. 2440) at 6); on the other, it appears they take issue with her statement that removals

are "rare" and that this testimony is *ipse dixit* (*id*. at 6-7). Either way, her "removal" testimony is neither and should be rejected for two reasons.

First, the significance of the testimony excerpted on page six of Plaintiffs' memorandum is unclear. Dr. Tomezsko is merely agreeing with Plaintiffs' counsel that removing the TVT entirely would require aggressive dissection and that there is no guarantee it can be done. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 64:8-17. The excerpted testimony has nothing to do with Dr. Tomezsko's testimony about how "rare" it may be to remove the TVT entirely. Even if this testimony can be "interpreted in two distinct ways" as Plaintiffs claim (Pls.' Mem. (Dkt. 2440) at 6)—and it cannot—this would be a matter for cross examination, not exclusion. Plaintiffs provide no authority to the contrary. Plaintiffs' argument can be rejected outright on this basis alone.

Second, Dr. Tomezsko's "removal" statements are based on her experience as a pelvic-floor surgeon and her interactions with other surgeons. She is relaying personal knowledge of what she has observed in practice. Ex. 1, Tomezsko 6/27/16 Dep. Tr. 62:14-64:7 (testifying about her knowledge of physicians who have removed the entire TVT device, which she gained from "patient cases"). This is not a *Daubert* issue.

IV. Relying on the Cochrane Review is scientifically sound.

Plaintiffs take issue with Dr. Tomezsko's reliance on the 2015 Cochrane Review because it includes data about other devices besides the TVT. *See* Pls.' Mem. (Dkt. 2440) at 7. Plaintiffs' argument should be rejected for three reasons.

First, Dr. Tomezsko acknowledged that, while the Cochrane Review meta-analysis includes "various midurethral slings," it is "heavily weighted upon the TVT data"; indeed, "[t]he vast majority of the data that's used is the TVT Retropubic." Ex. 1, Tomezsko 6/27/16 Dep. Tr. 123:14-21. Plaintiffs' attempt to characterize the 2015 Cochrane Review as literature that cannot

support Dr. Tomezsko's opinions is wrong. The Cochrane Review contains important information about the TVT upon which Dr. Tomezsko can reliably rely in formulating her opinions.

Second, Plaintiffs' argument, in truth, takes issue with Dr. Tomezsko's interpretation of the 2015 Cochrane Review, which is not a basis to exclude her opinions based on that literature; instead, it is a matter for cross-examination. *Tyree*, 54 F. Supp. 3d at 552 ("As the gatekeeper of expert testimony, [the Court] need not concern [it]self with the 'correctness of the expert's conclusions' and should instead focus on the 'soundness of his methodology.'" (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995))). Indeed, even if the medical literature is "not seamlessly align[ed]" with an expert's interpretation of a study, her methodology is not rendered unreliable as long as her interpretation is plausible. *Hovey v. Cook Inc.*, No. 2:13-cv-18900, 2015 WL 1405565, at *5 (S.D.W. Va. Mar. 26, 2015); *see also United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) ("The court need not determine that the proffered expert testimony is irrefutable or certainly correct."); *Wise*, 2015 WL 521202, at *21 ("The plaintiffs, instead, focus their arguments on why Dr. Clark's ultimate conclusion—that degradation does not occur—is wrong according to other sources. However, under *Daubert*, the court is not to decide whether an opinion is scientifically correct; it is to evaluate the method a proffered expert uses in reaching that opinion.").

Finally, this Court has found no reliability impediment for an expert to rely on studies that involve different mesh products. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582206, at *2-3 (S.D.W. Va. Sept. 1, 2016) (denying motion to exclude testimony of Dr. Moore based on studies involving different mesh products). Because the Cochrane Review analyzes the treatment of conditions that are at issue in this litigation, it

naturally provides a reliable basis from which Dr. Tomezsko can ground her opinions regardless of its discussion of other products.

Because Plaintiffs' challenge here essentially goes to Dr. Tomezsko's conclusions—not her methodology—their arguments fall outside the scope of a *Daubert* analysis and should be rejected.

V. Dr. Tomezsko's opinions are not limited to those she expressed in her deposition, but include those stated in her report.

Plaintiffs' last challenge is equally specious. Without analysis of any kind, Plaintiffs merely point to four statements that Dr. Tomezsko made during deposition and conclusorily state that Dr. Tomezsko's opinions at trial should be limited to this testimony. *See* Pls.' Mem. (Dkt. 2440) at 8. Plaintiffs cite to no legal authority of any kind to support this vague "argument," nor can they. Indeed, is this were true, there would be no need to exchange expert reports and the opinions of experts never deposed would be inadmissible at trial.

But this is not the law, nor should it be. Experts in this litigation are deposed under strict time limitations. The opinions expressed by the various experts are expounded upon in their reports, not depositions. It would be unfair, and contrary to the rules of civil procedures and evidence to limit an expert's opinions to those expressed in deposition. Indeed, nothing in Rules 26, 702, or 703 support such a position.

Even to the extent that Plaintiffs' argument could be construed as alleging that Dr. Tomezsko's opinions expressed at deposition were inconsistent with those expressed in her report—and nothing in Plaintiffs' brief says as much—any discrepancies between the two are matters for cross-examination, not a basis for exclusion. *Eghnayem*, 57 F. Supp. 3d at 678; *see also In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4473455, at *3 (S.D.W. Va. Sept. 1, 2016) (finding any inconsistency between an expert's report

and deposition to be a matter for cross-examination); *see also id*. at *4 (noting, as a recurring issue, that "inconsistent testimony . . . is more appropriately handled via cross-examination").

Plaintiffs simply have no legal basis to claim that Dr. Tomezsko's opinions should be limited to those expressed at her deposition. This extreme position should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 11, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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